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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,592	01/12/2007	Thomas J. Gardella	00786/538001	2201
21559	7590	10/14/2009		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110				
EXAMINER				
TELLER, ROY R				
ART UNIT		PAPER NUMBER		
1654				
NOTIFICATION DATE		DELIVERY MODE		
10/14/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

### Office Action Summary

**Application No.**

10/549,592

**Applicant(s)**

GARDELLA ET AL.

**Examiner**

ROY TELLER

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 27-56 is/are pending in the application.
- 4a) Of the above claim(s) 28-32, 37-49 and 51-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 27, 33-36, 50 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date 4/07, 8/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election with traverse of Group I, claims 1-36 and the species of SEQ ID NO: 7, in the reply filed on 8/3/09 is acknowledged. The traversal is on the ground(s) that claim 1 has been amended to require that the peptide of instant claim 1 include at least one alpha-helix-stabilizing residue. This is not found persuasive because the instant restriction requirement is drawn to a peptide (Group I) and methods of use (Groups II, III, and IV). Therefore, Shimizu's peptide sequence disclosure still reads on the instant peptide comprising the instant formula or a fragment thereof. See, for example, restriction requirement, page 3, 1<sup>st</sup> paragraph.

The requirement is still deemed proper and is therefore made FINAL.

Applicant state that the elected species, SEQ ID NO: 7, reads on claims 1, 27, 33-50 and 56. Claims 28-32, 37-49, and 51-55 are withdrawn as being drawn to non-elected inventions.

Claims 1, 27, 33-36, 50 and 56 are under examination.

### ***Information Disclosure Statement***

The information disclosure statements, received 4/20/07 and 8/12/09, are acknowledged. A signed copy of each is enclosed hereto.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 33-36, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong (WO 97/02834).

The instant invention is drawn to a biologically active peptide, parathyroid hormone, comprising the formula of SEQ ID NO: 1, or a fragment thereof, wherein at least one peptide is an alpha helix stabilizing residue.

Dong discloses peptide variants of fragment (1-34) of parathyroid hormone, in which at least one amino acid residue is alpha-aminoisobutyric acid (Aib), an alpha helix stabilizer. See, for example, abstract, page 2, page 6, page 20, claim 1, page 25, claim 18, page 27, claim 21 and page 29, claim 28.

Therefore, the cited reference is deemed to anticipate the instant claims above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 27, 33-36, 50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong (WO 97/02834).

The instant invention is drawn to a biologically active peptide, parathyroid hormone, comprising the formula of SEQ ID NO: 1, or a fragment thereof, wherein at least one peptide is an alpha helix stabilizing residue.

Dong beneficially discloses peptide variants of fragment (1-34) of parathyroid hormone, in which at least one amino acid residue is alpha-aminoisobutyric acid (Aib), an alpha helix stabilizer. See, for example, abstract, page 2, page 6, page 20, claim 1, page 25, claim 18, page 27, claim 21 and page 29, claim 28.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute an alpha helix stabilizer in a peptide in order to increase binding affinities based upon the beneficial teachings provided by Dong, as discussed above. If not expressly taught, the adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary.

### ***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT  
1654  
10/9/09

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655